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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/764,915

01/26/2004

Jose Vicente Murillo Garrido

9256-20US(003/PCT/02-V)

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7590

12/03/2008

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

12/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/764,915	Applicant(s) MURILLO GARRIDO ET AL.	
	Examiner Sabiha Qazi	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 January 1938.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 15-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 35-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 15-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Non-Final Office Action

Claims 1-38 are pending. No claim is allowed at this time.

Amendments are entered.

Summary of this Office Action dated Saturday, November 22, 2008

1. Information Disclosure Statement
2. Copending Applications
3. Specification
4. 35 USC § 112 Scope of Enablement Rejection
5. Response to Remarks
6. Communication

Information Disclosure Statement

No IDS has been filed in this application. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

35 USC § 112 --- First Paragraph scope OF Enablement Rejection

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full,

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clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-14 and 35-38 (in-part) rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds containing epoxide ring (as exemplified and elected), does not reasonably provide enablement for the preparation of thousands of compounds as has been claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Following reasons apply:

3. To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by “undue experimentation,” the Federal Circuit has stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention.

PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).¹

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

¹ As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is “undue”, not

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The nature of the invention

The invention relates to a process of making the steroidal compounds with large number of substituents and the intermediates.

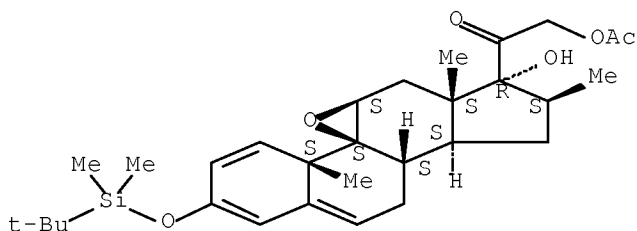
The amount of direction or guidance provided and the presence or absence of working examples

The specification discloses the preparation of epoxy compounds such as cited below.

RN 494870-05-2 ZCAPLUS

CN Pregna-1,3,5-trien-20-one, 21-(acetyloxy)-3-[[[(1,1-dimethylethyl)dimethylsilyl]oxy]-9,11-epoxy-17-hydroxy-16-methyl-, (9 β ,11 β ,16 β)- (9CI) (CA INDEX NAME)

Absolute stereochemistry.



“experimentation”.

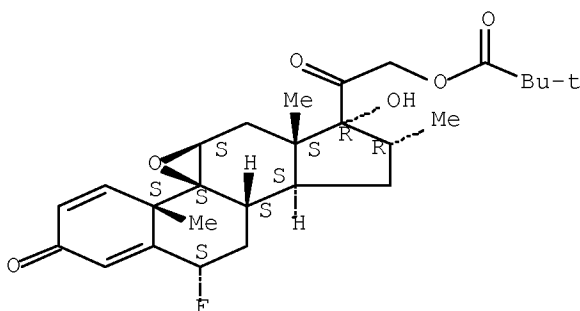
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RN 2135-16-2 ZCAPLUS

CN Pregna-1,4-diene-3,20-dione, 21-(2,2-dimethyl-1-oxopropoxy)-9,11-epoxy-6-

fluoro-17-hydroxy-16-methyl-, (6 α ,9 β ,11 β ,16 α)- (9CI)
(CA INDEX NAME)

Absolute stereochemistry.



The amount of direction provided by the inventor: The inventor provides very little direction in the instant specification. Only limited substituents on the compounds are prepared and disclosed. There are no compounds other than C as epoxy ring. The availability of the starting material that is needed to prepare the invention as claimed is also at issue here. As per MPEP 2164.01 (b): A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism

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is available only after extensive screening. The Court in In re Ghiron, 442 F.2d 985,991,169 USPQ 723,727 (CCPA 1971), made clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. In re Howarth, 654 F.2d 103, 105,210 USPQ 689, 691 (CCPA 1981). There are no starting materials provided with respect to the various substituents.

The existence of working examples: The instant specification does not have any working examples with respect to the various substituents as given above. The state of the art indicates that even when the reactants are similar, and the reaction conditions are the same, it is not necessary that it would form the same products.

The specification provides no direction or guidance for practicing the claimed invention in its “full scope” i.e. compounds not containing epoxy ring.

The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence

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of experimental evidence one skilled in the art would not be able to make and use the invention. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the claimed invention in its “full scope” a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Response to Remarks

Applicant's response and election of group VII, claims 1-14 and 35-38 wherein C ring represents the second structure (epoxide) with traverse is hereby acknowledged. The elected species is not a single compound therefore it is unclear what applicants mean by OP' and R4 at 16 and 17-positions. This is not the species. This includes hundreds of compounds. Applicant's arguments regarding restriction requirement has been fully considered but was not found persuasive. The search for intermediate compounds as claimed is not the same as the process of making the compounds. It will be burden on the examiner to search all the different inventions for the reason cited in the previous office action. Applicants argument are mainly based upon assuming that this is national stage application. This application is not a 371 application. Therefore the

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argument about the common property is not relevant. The restriction requirement was done based on groups. This was not the election of species. Species election was requested from the elected group to start the search and was not limited to species.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 15-25, drawn to steroidal compounds of formula IV when C represents 1st structure in line 8 on page 30 and D ring represents any one structure of D of claim 15.
- II. Claims 15-25, drawn to steroidal compounds of formula IV when C represents 2nd structure in line 8 on page 30 D ring represents any one structure of D of claim 15.
- III. Claims 15-25, drawn to steroidal compounds of formula IV when C represents 3rd structure in line 8 on page 30 D ring represents any one structure of D of claim 15.
- IV. Claims 15-25, drawn to steroidal compounds of formula IV when C represents 4th structure in line 8 on page 30 D ring represents any one structure of D of claim 15.

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- V. Claims 26-34 drawn to process of making the compounds of formula IV (one process of each group I-IV will be joined with the elected group of compounds.
- VI. Claims 1-14 and 35-38 are drawn to process of making the compounds of formula (I) when C represents 1st structure and D ring represents any one structure of D.
- VII. Claims 1-14 and 35-38 are drawn to process of making the compounds of formula (I) when C represents 2nd structure D ring represents any one structure of D.
- VIII. Claims 1-14 and 35-38 are drawn to process of making the compounds of formula (I) when C represents 3rd structure and D ring represents any one structure of D.
- IX. Claims 1-14 and 35-38 are drawn to process of making the compounds of formula (I) when C represents 4th structure and D ring represents any one structure of D.

In each group Applicants have to elect one C and one D ring and one single species from the elected group.

The inventions are distinct, each from the other because of the following reasons:

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2. Inventions of Group I to IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case that the product as claimed can be made by another and materially different process.

3. Inventions of group V and VI to IX are directed to to processes of making. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed the inventions do not overlap in scope, i.e., are mutually exclusive. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

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4. Each group requires a separate search and the inventions are different in structures and process of making. One reference use to reject the invention of one group may not be used to reject any other group on the same basis. It would be a burden on the Examiner to search all the invention in one application. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims Groups I to IV (Product, compounds) and V (process of making). Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected

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process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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5. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

The examiner has required restriction between product and process claims Groups I to IV (Product, compounds) and V

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(process of making). Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is

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advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/
Primary Examiner, Art Unit 1612